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IN RE: :SUPERIOR COURT OF
PELVIC MESH/GYNECARE :NEW JERSEY
LITIGATION :LAW DIVISION -
:ATLANTIC COUNTY
:MASTER CASE 6341-10
:CASE NO. 291 CT
:
:Civil Action

6 CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
7 CONFIDENTIALITY
8 EXPERT WITNESS TESTIMONY OF MILES MURPHY, M.D.

9 - - -
10 November 30, 2012

Videotaped deposition of MILES MURPHY,
M.D., held at BUTLER SNOW, 500 Office Center Drive,
Suite 400, Blue Bell Conference Room, Fort Washington,
Pennsylvania, commencing at approximately 9:43 a.m.,
before Margaret M. Reihl, a Certified Realtime
Reporter, Certified Court Reporter and Notary Public
for the State of New Jersey and Commonwealth of
Pennsylvania.

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1 patient and how you're going to actually, for example,
2 trim the mesh and implant the mesh, correct?

3 MR. SNELL: Object to the form.

4 THE WITNESS: Correct.

5 MR. SLATER: What is your objection?

6 MR. SNELL: Template, I'm not sure what
7 you mean by template.

8 MR. SLATER: You don't know what the
9 word template means, counsel; is that what you're
10 saying in good faith on this record?

11 MR. SNELL: Yes, as to the Prolift® as
12 a template.

13 BY MR. SLATER:

14 Q. Okay. You understood what I meant, right?

15 A. I think I did.

16 Q. Let's go back to your Exhibit Murphy-1.

17 Page 32 is a bibliography. What does that
18 bibliography represent? It goes from Page 32 to 38.
19 What does that represent?

20 A. It represents the resources that I used in
21 drafting my report.

22 Q. After the bibli -- well, rephrase.

23 When you say the resources you used in
24 drafting your report, what do you mean by that?

25 A. Meaning that when I wrote the report, most

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1 of the opinion, most of the body of the report is
2 based on scientific data, published data and whenever
3 I used, for instance, a paper that had been published,
4 I referenced that in the report.

5 Q. So whatever clinical data you relied on in
6 writing your report is found in the bibliography?

7 A. No.

8 Q. Well, besides what's referenced in the
9 bibliography, what other clinical data did you rely on
10 in forming your opinions in this case?

11 A. My own medical experience, my own clinical
12 experience and that of my colleagues.

13 Q. To the extent that clinical or medical data
14 is published someplace and you relied on it to some
15 extent in forming your opinions, is it listed in the
16 bibliography?

17 A. For this first report, yes.

18 Q. At the time you wrote and signed your first
19 report, which is Murphy-1, the published or documented
20 clinical data that you were relying on was listed in
21 the bibliography from Page 32 to 38, correct?

22 MR. SNELL: Objection, form.

23 THE WITNESS: That was a pretty long
24 question, but I think the answer is yes.

25 BY MR. SLATER:

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1 Q. Okay. Well, what I was saying is at the
2 time you formed your opinions that are set forth in
3 Murphy-1, the first report you authored, to the extent
4 that you relied on data that is actually published,
5 actually documented, are those sources of data listed
6 in the bibliography?

7 A. The ones that I specifically referenced are
8 in the bibliography. It doesn't mean that I may not
9 have read something else in my life, in my last eight
10 and a half years of practice and used that in forming
11 my opinions, but when I specifically, for instance,
12 quote a paper, I put it in my bibliography.

13 Q. You understand one of the purposes of
14 writing your report is to give notice to myself and
15 other attorneys as to what your opinions are and what
16 you relied on in forming those opinions, correct?

17 A. Right.

18 Q. You understood that, right?

19 A. I understand that generally you don't want
20 to be surprised at court if I, all of the sudden, want
21 to reference something and I haven't mentioned it
22 before.

23 Q. Well, not just generally, but you understand
24 that the court rules actually say that if you're going
25 to rely on something, you're supposed to actually

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1 disclose what you relied on in forming your opinions;
2 did you understand that when you authored this report?

3 A. I think so. I'm not a lawyer but --

4 Q. When you wrote this report and you attached
5 this bibliography to it --

6 A. Yes.

7 Q. -- did you intend to give notice to myself
8 and other people in this case as to what published or
9 documented clinical data you were relying on in
10 forming your opinions in the report?

11 MR. SNELL: Objection, go ahead.

12 THE WITNESS: When I wrote the report
13 and compiled the bibliography, I wanted to make sure
14 that if there was important literature that I wanted
15 to reference in my report that I included in the
16 bibliography. That was my main purpose of doing the
17 bibliography.

18 BY MR. SLATER:

19 Q. So at the time that you wrote the report,
20 any literature that was -- rephrase.

21 So at the time you wrote this report and
22 signed it, any published data, clinical data that you
23 felt was important to you in forming your opinions,
24 you listed in the bibliography?

25 MR. SNELL: Objection, form.

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1 THE WITNESS: Not necessarily. I

2 simply --

3 BY MR. SLATER:

4 Q. Well, tell me.

5 A. Those were the ones that I used when I wrote
6 the report.

7 Q. Well, is there something that you relied on
8 that is published data at the time you wrote this
9 report that's not listed in the bibliography that you
10 can point to right now?

11 A. That I relied on in actually writing this
12 version of the report?

13 Q. Yes.

14 A. I can't point to anything like that right
15 now.

16 Q. Okay. After the bibliography there is a
17 section titled "Additional List of Materials - Miles
18 Murphy, M.D."

19 Do you see that?

20 A. Yes.

21 Q. What does that list represent?

22 A. That represents additional material that I
23 thought we might want to be able to reference in my
24 testimony on this case.

25 Q. Did you review all of the materials listed

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1 on this list of additional materials before you signed
2 that report?

3 A. Briefly, yes.

4 Q. When you say "briefly," what do you mean?

5 A. I looked at them.

6 Q. Well, when you say "looked at them," for
7 example, there could be a deposition transcript, and
8 I'll take an example from this additional list of
9 materials. There's the deposition transcript of
10 exhibits of Piet Hinoul, P-i-e-t H-i-n-o-u-l, listed.

11 Did you read that entire transcript and
12 exhibits?

13 A. No, I did not. That's a very long --
14 there's a couple volumes of that, but I had certainly
15 reviewed it.

16 Q. Well, when you say you reviewed it, what
17 does that mean?

18 A. I read some of it.

19 Q. How many pages of it did you read?

20 A. I don't recall.

21 Q. Did you read more than ten pages of that
22 deposition?

23 A. Yes.

24 Q. But you can't tell me beyond that what you
25 specifically read?

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1 A. I can remember some of the things that I
2 read in it.

3 Q. Well, was there -- well, we'll come back to
4 that.

5 Did you read -- it says -- rephrase it.

6 It says Jessica Shen, deposition transcript
7 with exhibits.

8 Did you read the entire deposition and
9 exhibits?

10 A. No.

11 Q. It says Judi Gauld, deposition transcript
12 with exhibits.

13 Did you read the entire deposition and
14 exhibits?

15 A. I did not.

16 Q. It says David Robinson, deposition
17 transcript with exhibits.

18 Did you read the entire deposition and read
19 all the exhibits?

20 A. No.

21 Q. And with regard to Jessica Shen, Piet
22 Hinoul, Judi Gauld and David Robinson's deposition
23 transcripts that are listed here, did you actually
24 watch the videos of their depositions?

25 A. No.

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1 Q. Didn't see any of those videos, correct?

2 A. Correct.

3 Q. Have you seen the video of anyone's
4 deposition that's ever been taken in this case?

5 A. No.

6 Q. Did you ever ask to see any of the videos of
7 the actual deposition testimony of any witness in this
8 case?

9 A. No.

10 Q. In writing the report, which we marked as
11 Murphy-1 -- well, rephrase.

12 This list of additional materials, are these
13 basically other materials that you wanted to list in
14 case you wanted to mention them during trial so you
15 could say, hey, you know that I listed them; is that
16 basically the purpose?

17 MR. SNELL: Object to form. Go ahead.

18 THE WITNESS: I think that's a fair
19 assessment because from the time I drafted my report,
20 there were a lot of depositions and your -- you know,
21 the plaintiffs' expert had referenced things, and I
22 wanted to make sure that I could reference other
23 things as well.

24 BY MR. SLATER:

25 Q. Okay. Is it fair to say that at the time

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1 you wrote your first report, which is Murphy-1, you
2 had not read all of the materials listed on the
3 list -- additional list of materials?

4 A. Yes.

5 Q. Is it fair to say you did not rely on all
6 the materials listed in the additional list of
7 materials when you actually formed your opinions?

8 A. I would say that I didn't rely on all of
9 them, but it's very likely that I would have read some
10 of the other additional materials, just not quoted
11 them in my bibliography.

12 Q. When you wrote your report, you set forth
13 opinions, and I'm talking about your first report,
14 Murphy-1, you set forth certain opinions in the
15 report, correct?

16 A. Correct.

17 Q. Were those all of the opinions you had
18 formed with regard to this litigation at the time that
19 you authored that report?

20 A. I don't know that I -- I mean, I have lots
21 of opinions about this case. I don't know that every
22 single solitary one was listed in the report.

23 Q. You understood that one of the purposes of
24 your report was to give notice to attorneys in the
25 litigation like myself of what your opinions were,

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1 correct?

2 A. Correct.

3 Q. Okay. Did you endeavor, when you wrote this
4 report, to list each of the opinions that you had
5 formed at the time that you authored the report; was
6 that your goal?

7 A. My goal was simply to write a report that
8 reflected my views of Prolift® in this case.

9 Q. Okay. And the opinions set forth in your
10 first report, Murphy-1, accomplished that, from your
11 perspective?

12 A. I think so, but I think that in looking at
13 other people's depositions, there may have been things
14 that they covered that I didn't think were necessarily
15 essential to cover in my first report and, therefore,
16 wanted to have some supplemental material later on.

17 Q. At the time that you authored your first
18 report --

19 A. Yes.

20 Q. -- the day that you put your signature, your
21 electronic signature on there, typed your name in, did
22 that represent the opinions you had formed as of that
23 point in time with regard to this litigation?

24 MR. SNELL: Objection, form.

25 THE WITNESS: Yes.

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1 BY MR. SLATER:

2 Q. In the report you listed many facts from
3 various sources of information that you referred to in
4 the report, correct?

5 A. Yes.

6 Q. Did you, in writing the report, attempt to
7 list those facts that you felt were most important to
8 you in forming your opinions as set forth in the
9 report?

10 A. I think that's a fair thing to say.

11 Q. If you read something in one of the
12 depositions that you listed in your additional
13 materials -- rephrase.

14 Let me ask you this: Had you read any parts
15 of the Jessica Shen, Piet Hinoul, Judi Gauld and David
16 Robinson deposition transcripts at the time you wrote
17 the report, or did you just list them at the time
18 because it was something that you thought you might
19 want to reference later?

20 A. When I wrote Murphy-1?

21 Q. Yes.

22 A. I believe I had not seen those when I wrote
23 Murphy-1.

24 Q. At the time you wrote Murphy-1 and signed
25 it, had you read all of the expert reports that are

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1 listed below the list of deposition transcripts, or
2 were those things you listed because you planned to
3 read them at a later date?

4 A. I'm sorry. Which are you referring to? Are
5 you referring to something in the bibliography?

6 Q. I'm looking the list of additional
7 materials.

8 A. Oh, additional materials. I'm sorry. Can
9 you repeat the question then?

10 Q. Sure. Go to the page where you listed the
11 four deposition transcripts?

12 A. Yes.

13 Q. Because right below that are a list of
14 expert reports.

15 A. Yes.

16 Q. Might as well turn to it.

17 A. Yeah.

18 Q. Right before your CV.

19 Are you with me now?

20 A. Yes.

21 Q. On the last page of the list of additional
22 materials, there's a list of expert reports under
23 three headings, expert general reports, Plaintiff
24 Gross, Plaintiff Wicker.

25 Do you see that?

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1 A. Yes.

2 Q. At the time that you authored Murphy-1, your
3 first report, had you read those, or did you simply
4 list those in the list of additional materials because
5 they were things that you intended to read later?

6 A. The Anne Weber expert report, I believe I
7 had that at the time I drafted Murphy-1. I certainly
8 did not read every page of that report, but I had read
9 a significant amount of it. I don't think that I had
10 read any of the other reports at the time I drafted
11 Murphy-1.

12 Q. Okay. With regard to the list of additional
13 materials, with the exception of the deposition
14 transcripts and expert reports, which you've already
15 spoken about, are you able to go through this list if
16 you needed to, and would you be able to tell me which
17 things you had looked at at the time you wrote the
18 report versus those things that you just listed
19 because you intended to look at them later, or would
20 that be something you would be unable to do?

21 A. I think I'd be unable to do that.

22 Q. Okay. To the extent that you felt that
23 something was important enough to actually reference
24 it in the report itself as having been relied on,
25 those materials are listed in the bibliography,

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1 BY MR. SLATER:

2 Q. You've never worked directly at a medical
3 device company, correct?

4 A. Correct.

5 Q. Never worked at a pharmaceutical company,
6 correct?

7 A. Correct.

8 Q. You've never been involved in a design
9 control process prelaunch of a medical device,
10 correct?

11 A. I've been involved in -- I think they called
12 it a validation study for TVT-Secur®. They had me
13 come in and look at -- jeez, it's been many years, but
14 I think it was along the lines of wanting to
15 standardize technique so that it can be, you know,
16 printed in the IFU, things like that. I think it was
17 along those lines, but I was not -- I was a consultant
18 at that point. I was not employed.

19 Q. You've never been involved in structuring or
20 implementing a design control process for a medical
21 device from the medical device company perspective,
22 correct?

23 A. No. I don't really even know what design
24 control process is.

25 Q. Are you familiar with what the term DDSA is?

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1 A. I'm not.

2 Q. Are you familiar with the term FMEA, failure
3 modes and effects analysis?

4 A. No.

5 Q. And DDSA, just for the record, device design
6 safety assessment, is that a term you're familiar
7 with?

8 A. No.

9 Q. Did you look at the DDSA or FMEA analyses
10 for the Prolift® in this case?

11 A. I did not.

12 Q. And you're not going to offer any opinions
13 on that subject at all, correct? If you didn't look
14 at them, you're not going to offer opinions, right?

15 A. If you show it to me, I guess maybe I would,
16 but, otherwise, no, I'm not going to offer them in my
17 report.

18 Q. It's not something you've ever done, as we
19 sit here now, right?

20 A. No.

21 Q. Have you ever been involved in authoring a
22 clinical expert report within a medical device company
23 with regard to a medical device that was going to be
24 on the market or was already on the market?

25 A. A clinical device --

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1 saying you haven't read it and have no opinions now, I
2 will not be giving it to you.

3 A. Okay.

4 Q. Unless you want to really stay late tonight.

5 To your knowledge, were the exposure rates
6 in the French and US TVM study accurately counted or
7 undercounted? Do you have any information one way or
8 the other on that?

9 A. I do not.

10 Q. That's not something you tend to offer
11 opinions on, correct?

12 A. I tend to offer opinions on whether or not I
13 believe what I see is published or presented at
14 meetings.

15 Q. Without looking at the underlying data and
16 studying that question, you're not in a position, as
17 you sit here now, to offer an opinion on whether or
18 not the exposures that occurred in the French and US
19 TVM studies were accurately reported in the published
20 manuscripts, correct?

21 MR. SNELL: Objection, form.

22 THE WITNESS: I guess I'd have trouble
23 agreeing to that. I mean, most doctors that I know
24 that dedicate their time to taking care of people and
25 going through the trouble of producing research, and I

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1 tend to believe what they produce, but I wasn't there
2 standing next to them when they looked to see whether
3 or not there was an exposure and checked off on the
4 sheet.

5 BY MR. SLATER:

6 Q. You don't have information one way or the
7 other specific to whether or not the exposure rates
8 that were actually reported with regard to the TVM
9 study were representative of what the underlying data
10 showed; is that a true statement?

11 MR. SNELL: Objection, form.

12 THE WITNESS: I guess.

13 MR. SNELL: You're not here to guess.
14 If you don't understand his question, just ask him to
15 rephrase it.

16 THE WITNESS: Are you saying do I think
17 that they -- that the doctors reported a certain
18 erosion rate and they changed it?

19 BY MR. SLATER:

20 Q. No. What I'm asking is this: You read the
21 exposure rates that were reported in connection with
22 the TVM studies, correct?

23 A. Correct.

24 Q. But you haven't looked at the underlying
25 data to try to form an opinion about whether or not

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1 what was reported in the articles that you read is
2 actually reflective of what was documented in the
3 underlying data?

4 A. And when you say "the underlying data," what
5 are you referring to?

6 Q. The case specific -- patient specific forms
7 for each patient that show each exam that was done and
8 what was recorded with regard to whether or not an
9 exposure existed at a certain time.

10 A. Right. I have not -- to save us some time
11 maybe, I have not reviewed any case report forms that
12 the physicians or the patients filled out. I have not
13 reviewed their database. I have not reviewed their --
14 you know, their SAS database or anything like that. I
15 did not have any access to the primary data, only what
16 was published.

17 Q. Okay. So you wouldn't be forming an opinion
18 about whether or not the published data reflects what
19 the actual raw data in the case specific forms shows,
20 correct?

21 MR. SNELL: Objection, form.

22 THE WITNESS: Only to what I just
23 responded before, that I tend to trust doctors that do
24 this work.

25 BY MR. SLATER:

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1 Q. You tend to trust when something is
2 published or presented at a meeting, you tend to trust
3 that the data being given is accurate, right?

4 A. Correct.

5 Q. If it were to turn out later that the data
6 was inaccurate, that would raise questions about the
7 reliability of the conclusions about that reported
8 data, correct?

9 A. In general, yes.

10 Q. With regard to the recurrence rates, you did
11 not review the raw data, so you have no basis to offer
12 an opinion one way or another as to whether the
13 reported recurrence rates accurately reflect what's in
14 the underlying data, correct?

15 MR. SNELL: Objection, form.

16 THE WITNESS: Again, I did not review
17 any of the primary data on any outcome of the TVM
18 study.

19 BY MR. SLATER:

20 Q. Let's change gears for a second and talk
21 about Gynemesh® PS -- rephrase.

22 Let me ask you one or two other questions
23 about TVM, because I want to try to put this aside.

24 Do you know how Ethicon utilized the TVM
25 study in connection with the Prolift®; meaning from

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1 Ethicon's perspective, what, if any, reliance was
2 placed on the TVM studies?

3 A. I do not know.

4 Q. Let me ask you about the Gynemesh® PS study.
5 Do you know what that is?

6 A. I know that a study was reported in terms of
7 abstract form on the use of Gynemesh® if that's the
8 one you're referring to.

9 Q. Do you know any specific information about,
10 for example, how the Gynemesh® was used in that study?

11 A. I believe it was used both transabdominally
12 and transvaginally.

13 Q. Have you looked at any of the underlying
14 data, patient report forms or any of that with regard
15 to Gynemesh® PS study?

16 A. No.

17 Q. So you're not in a position to form any
18 opinions about whether what is actually reported in
19 the abstract or the white paper or the actual
20 documents that were produced following the Gynemesh®
21 PS study about whether that accurately reflects what
22 the data shows?

23 A. I will go back to my previous answer, only
24 in that I tend to trust that what I'm seeing published
25 is valid.

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1 Q. Beyond that you have never looked at the
2 underlying data to compare it to what was reported by
3 the authors of the -- or the investigators of the
4 Gynemesh® PS study, so you're not in a position to
5 form any specific opinions on whether or not the
6 reported results reflect the underlying data, correct?

7 MR. SNELL: Objection, form.

8 THE WITNESS: I was going to answer one
9 of your questions, and I was going to say I have not,
10 and by the end of the question it changed to a
11 different question.

12 BY MR. SLATER:

13 Q. Okay.

14 A. I have not reviewed any of the original
15 patient reports.

16 Q. You haven't reviewed any of the underlying
17 Gynemesh® PS data, correct?

18 A. Not that I know of.

19 Q. And you haven't ever compared the underlying
20 data to what was reported by the investigators in any
21 articles or abstracts, correct?

22 A. Correct.

23 Q. So you're not going to offer any opinions
24 about whether or not what was reported, either
25 abstracts or papers, reflects the underlying data

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1 because it's not something you've looked at, right?

2 A. Yes, only to -- it's the same question you
3 asked before in terms of only to the extent that I --
4 it's my opinion that I tend to trust that.

5 Q. Your assumption is that the reported results
6 would be accurate, but you've never actually looked at
7 it yourself to confirm that?

8 A. Correct.

9 Q. And you're not in a position to form a
10 specific opinion about whether it's correct. All you
11 have is your assumption, which is a general assumption
12 that people will only accurately report data?

13 MR. SNELL: Object to form.

14 THE WITNESS: Correct.

15 BY MR. SLATER:

16 Q. Do you know whether or to what extent
17 Ethicon relied on or utilized the Gynemesh® PS study
18 in connection with the Prolift®?

19 A. I do not know what Ethicon relied upon.

20 Q. Do you know what Ethicon relied on before it
21 marketed the Prolift® to make the decision the
22 Prolift® is safe and effective and should be released
23 for marketing to the public?

24 A. As we stated earlier, I've never been an
25 employee of Ethicon. I never worked in there. I

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1 never went to their meetings about how they were
2 deciding whether -- how to release Prolift®.

3 Q. And there's no specific deposition testimony
4 you recall seeing on that topic?

5 A. Not that I recall.

6 Q. And no specific documents that you saw on
7 that specific topic, as you sit here now, which would
8 indicate what specific information Ethicon relied on
9 to say, okay, this is a safe and effective product,
10 we're going to release the Prolift®?

11 A. Yeah, I mean, I've -- some of these
12 depositions are very long, and I know Piet Hinoul, I
13 think there was some discussion of that in his
14 deposition, but I don't have any specific
15 recollection. If you want to ask me something
16 specific, I'd be happy to answer.

17 Q. You're certainly not offering any opinions,
18 as you sit here now, with regard to what Ethicon may
19 or may not have relied on when they decided, yes, the
20 Prolift® is safe and effective, and we're going to
21 mark it to the world?

22 A. I could with a reasonable certainty surmise
23 that they relied upon Gynemesh® studies and TVM
24 studies, but, again, I wasn't there to know that for
25 sure.

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1 Q. That's just an assumption you're forming?

2 A. It's an educated assumption.

3 Q. Do you know what data was available to
4 Ethicon at the time the decision was made that the
5 Prolift® is safe and effective to be marketed?

6 A. I'm sorry. Could you repeat the question.

7 Q. Sure. Do you know what specific data was
8 available to Ethicon as of February, March 2005 when
9 they were actually now launching the Prolift®, what
10 they actually were relying on at the time they made
11 the decision, yes, it's safe and effective, yes, we
12 can market it?

13 A. I do not know what they were relying on.

14 Q. Since you don't know specifically what
15 they're relying on, you're not going to offer any
16 specific opinions about whether that data was
17 sufficient or not; fair statement?

18 MR. SNELL: Objection, form.

19 THE WITNESS: I'm happy to offer
20 opinions on the data that was present. I'm not going
21 to make an expert opinion as to what Ethicon was
22 relying on. I have no idea what they thought was
23 important.

24 BY MR. SLATER:

25 Q. My question is this: Since you don't know

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1 what Ethicon specifically was relying on when they
2 made that decision to launch the Prolift®, you
3 wouldn't be offering me an opinion about whether
4 something you're not familiar with was reasonable or
5 not, correct?

6 A. Not unless you give me some information
7 about what they knew and what they were relying upon,
8 and then I'd be happy to make an opinion on it.

9 Q. Well, this is my chance to ask you what you
10 know and what your opinions are.

11 So as you sit here now, you have no opinion
12 on that, correct?

13 A. Correct.

14 Q. Do you know Axel Arnaud? Did you ever meet
15 him?

16 A. I think I met him in an airport once.

17 Q. Attached to your supplemental report, which
18 we marked as Murphy-2, is a list of transcripts,
19 expert reports and literature and then an other
20 section, right?

21 A. I see that.

22 Q. Did you read all these materials before
23 signing this report on November 28, 2012?

24 A. What I will say is I've been bombarded with
25 documents in the last two weeks. I open the Fed Ex

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1 A. I may have spoken to them personally. I
2 don't know that we were speaking about that. I know
3 there are people like at the Mayo Clinic and Cleveland
4 Clinic that get a lot of these referred in to them,
5 and I've certainly spoken to a lot of those
6 physicians.

7 I don't know that -- I know that a lot of
8 people have come to me at meetings and said, hey, you
9 know, we're seeing more problems with these types of
10 things than what you guys are reporting. And I know
11 Matt Barber, his group did a presentation on, you
12 know, removing mesh and things like that and what we
13 call tips and tricks in terms of techniques for doing
14 that.

15 Q. Let me come back to your report, your
16 supplemental report. We were talking about the list
17 of materials.

18 Are there materials on this list that you
19 probably have not read at this point?

20 A. Certainly in their entirety, yes.

21 Q. Are there materials on this list that you
22 probably just scanned very quick and couldn't even
23 tell me what those materials said, as you sit here
24 now?

25 A. As I sit here now, probably yes.

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1 Q. Are you able to point out, other than
2 Dr. Margolis' transcript and Dr. Elliott's transcript,
3 which you said you believe you read completely, and
4 Dr. Lucente's you said you read --

5 A. 10%.

6 Q. 10% -- can you give me any quantification of
7 how much of these other materials you reviewed?

8 A. It would be something pretty close to a
9 guess. Let me say this, less than 20% of all of them.

10 Q. In the list of materials there's literature,
11 and on the second page of that there's a series of
12 articles towards the middle, where the first author in
13 four straight is Klinge, K-l-i-n-g-e.

14 Do you see that?

15 A. I do.

16 Q. Do you know who that is?

17 A. He's one of these names that I see in
18 regards to mesh, basic science regarding mesh.

19 Q. Anything else?

20 A. I don't know him personally. I don't even
21 know if it's a man or a woman, to be honest with you.

22 Q. Have you made a point of studying the basic
23 science with regard to polypropylene mesh and how it
24 interacts within the woman's pelvis?

25 A. I certainly have tried to keep up on all the

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1 standpoint.

2 Q. Is there -- well, let me ask you this: The
3 standard you just gave me of what you think should be
4 in an IFU, is that just your own personal standard?

5 A. That was my opinion of what makes sense to
6 be in an IFU.

7 Q. That's your own personal opinion, not based
8 on any other information you've read or seen, correct?

9 A. Correct.

10 Q. It's just your own personal viewpoint, your
11 own personal standard, correct?

12 A. Yes.

13 Q. With regard to what would need to be
14 included in the patient brochure with regard to risks
15 and benefits, to the extent you've drawn any opinions
16 in your report on that, again, is that based on your
17 own personal standard, your own personal opinion?

18 A. I do not -- I think the answer is yes
19 because I don't know any sort of legal guidelines by
20 which patient brochures are supposed to be produced.

21 Q. And do you have any information you can
22 share with me now that you gleaned from any Ethicon
23 documents or testimony where you saw what Ethicon
24 thought the standards were to determine whether or not
25 a risk or a benefit would need to be described and how

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1 it should be described in a patient brochure?

2 A. I don't recall seeing any standards that
3 they refer to.

4 Q. Did you see any testimony in any deposition
5 that you're relying on, as you sit here now, with
6 regard to what needs to be included in an IFU?

7 A. I do not recall seeing anything like that.

8 Q. So, again, with regard to the IFU and the
9 contents of the IFU, whatever opinion you're drawing
10 is just based on your own personal opinion, not based
11 on what any other standards may be or what anyone else
12 might think, correct?

13 A. Right. It's my expert opinion, not based on
14 outside information.

15 Q. And in your entire career, have you ever
16 been asked to determine what information needs to be
17 provided in an IFU?

18 A. Not that I recall.

19 Q. Have you ever in your career ever been asked
20 to give input on what should be in a patient brochure?

21 A. Not that I recall.

22 Q. So the first time you've ever offered such
23 opinions and done this type of analysis has been in
24 this case as an expert, correct?

25 A. Correct.

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1 A. Yes.

2 Q. Do you know, as you sit here now, based on
3 whatever you've reviewed, what the potential risks of
4 the Prolift® were from the perspective of what medical
5 affairs in Ethicon knew?

6 A. I do not know what medical -- what that
7 group knew.

8 Q. Would you assume that Ethicon medical
9 affairs would have more information about the overall
10 potential risks of the Prolift® than you would have?

11 MR. SNELL: Objection, form.

12 THE WITNESS: I don't know how that --

13 MR. SNELL: He's not here to assume.

14 MR. SLATER: Well, he is, actually.

15 You can answer.

16 THE WITNESS: I don't know if they'd
17 know more. I think they would know probably most that
18 I would.

19 BY MR. SLATER:

20 Q. As you sit here now, you don't know whether
21 Ethicon medical affairs -- well, rephrase.

22 As you sit here now, you don't know what
23 risks Ethicon medical affairs has testified to knowing
24 about at different points in time, correct?

25 A. I can't recall any testimony that I saw

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1 regarding that.

2 Q. You certainly didn't talk about that subject
3 in your reports, correct?

4 A. Correct.

5 Q. Did you in reading any of the materials that
6 you actually did read or review -- rephrase.

7 In any of the materials that you reviewed,
8 to the extent you reviewed any of the materials you've
9 listed, did you at any point see anybody from Ethicon
10 talk about knowing about risks where you said, well, I
11 didn't know that was a risk, I wasn't aware of that?
12 Did that ever happen?

13 A. Did it ever happen that someone at Ethicon
14 knew a risk that I wasn't aware of as a potential
15 risk?

16 Q. Right, where you read the depositions and
17 saw something to that effect?

18 A. Not that I know of.

19 Q. But, again, you've told me you didn't
20 read -- other than a couple depositions, you didn't
21 read any of them in their entirety, right?

22 A. Correct.

23 Q. For the most part, you just skimmed through
24 a few of them?

25 A. Correct.

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1 Q. Am I correct that you reviewed very little
2 by way of documents indicating what the people within
3 medical affairs at Ethicon thought at any particular
4 point in time?

5 A. What I'm saying is I got stacks of documents
6 within the last two weeks that were about 2 feet high,
7 and I have only gotten through a small percentage of
8 that.

9 Q. As you sit here now, you don't feel that you
10 have a good understanding of what the people in
11 medical affairs at Ethicon thought with regard to mesh
12 shrinkage, erosion or other topics?

13 A. If you read my report, I don't think
14 anywhere do I mention what the people in medical
15 affairs at Gynecare knew or didn't know.

16 Q. Let's turn to the page that at the top says
17 "Clinical impact of mesh shrinkage."

18 A. How far?

19 Q. It's about ten pages in or so.

20 A. What's the topic -- the title again?

21 Q. "Clinical impact of mesh shrinkage."

22 A. Not how to assess?

23 Q. It's right before that.

24 A. Right before that. I don't see anything
25 before that. I see how to assess mesh shrinkage,